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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,138	02/13/2002	Darrell R. Anderson	P 0280705 1995-30-0233CP1	7969

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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 11/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/073,138	ANDERSON ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-41 and 43-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-41 and 43-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 8/26/05, has been entered.
Claims 42 and 56 have been canceled. Claims 1-28 have been canceled previously.
Claims 29, 36-37, 41, 50-51 and 55 have been amended.

Claims 29-41 and 43-55 are pending and being acted upon presently.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Action will be in response to applicant's arguments, filed 8/25/05.
The rejections of record can be found in the previous Office Action, mailed 2/28/05.

3. The following is a quotation of the first paragraph of 35 U.S.C. ∋ 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Applicant's amended claims have obviated the previous rejection under 35 U.S.C. 112, first paragraph, enablement, except for the following with respect to "fragment thereof" as it reads on anti-CD28 antibody.

5. Claims 41 and 55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It has been well established in the art that the antigen specificity of an antibody resides in the antigen-binding fragments and not in other fragments (e.g. Fc fragments) of antibodies.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth.

The specification does not describe nor enable any fragment of an anti-CD28 antibody that will bind CD28, and, in turn, treat B cell lymphoma in combination with anti-CD80 antibodies, commensurate in scope with the claimed invention.

It would be unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue to practice the claimed methods of treating B cell lymphoma with combination therapy, where an antibody fragment lacks antigen specificity.

Applicant is invited to consider limiting the claimed fragments to antigen-binding fragments, provided there is written support in the specification as filed.

6. The amendment filed 8/26/05, is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention.

The added material which is not supported by the original disclosure is as follows:
SEQ. ID. Nos. 2, 5 and 6 as well as newly submitted Figure 5A and the Sequence Listing, filed 8/26/05.

Applicant's explanation is acknowledged.

However, in order to make the record clear and as applicant has offered,
a declaration attesting that the newly amended sequences is identical to the sequences of the original biological materials deposited with the ATCC and identified in the specification is required.

Applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the newly amended sequences are those sequences derived from the biological materials which are deposited and are derived from the biological materials specifically identified in the application as filed.

If not, then applicant is required to cancel the new matter in the reply to this Office Action.

7. Claims 33-35, 47-49 and 54 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

The specification as originally filed does not provide support for the invention as now claimed:
"SEQ ID NOS, 2, 5 and 6".

Applicant's explanation and direction to amending SEQ ID NOS. 2, 5 and 6 in the amendment, filed 8/29,05, is acknowledged.

However, in order to make the record clear and as applicant has offered,
a declaration attesting that the newly amended sequences is identical to the sequences of the original biological materials deposited with the ATCC and identified in the specification is required.

Applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the newly amended sequences are those sequences derived from the biological materials which are deposited and are derived from the biological materials specifically identified in the application as filed.

In the absence of a Declaration from someone in position to corroborate the fact,
the specification as filed does not provide a sufficient written description nor provide sufficient blazemarks nor direction for the instant methods encompassing the above-mentioned amendments to SEQ ID NOS. 2, 5 and 6, as they are currently recited. The instant claims now recite limitations which were not clearly disclosed in the specification as-filed, and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, which did not appear in the specification, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the new matter in the response to this Office action

Alternatively, applicant is invited to provide sufficient written support for the Alimitations≅ indicated above. See MPEP 714.02 and 2163.06.

Applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the newly amended sequences are those sequences derived from the biological materials which are deposited and are derived from the biological materials specifically identified in the application as filed.

If not, then applicant is required to cancel the new matter in the reply to this Office Action.

7. Claims 33-35, 47-49 and 54 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Given the ambiguity concerning the correct sequences associated with the 7C10 and 16C10 antibodies set forth above in the new matter rejections with respect to both the claims and the disclosure, claims 33-35, 47-49 and 54 are indefinite in that the proper sequences set forth in SEQ ID NOS. 2, 5 and 6 are unclear in the absence of a verified statement from a person in a position to corroborate the fact, and should state, that the newly amended sequences are those sequences derived from the biological materials which are deposited and are derived from the biological materials specifically identified in the application as filed.

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06.

8. Claims 29-41 and 43-55 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23-26, 32 and 37 of copending application USSN 09/758,173 essentially for the reasons of record.

Although the conflicting claims are not identical, they are not patentably distinct from both sets of claims appear to drawn to the same or nearly the same methods of treating B cell lymphoma with the same or nearly the same CD80-specific antibodies that inhibit the binding of B cells and T cells via the CD80/CD28 pathway without inhibiting the binding of CD80 to CTLA-4. The instant recitation of "inhibiting or preventing T cell / B cell interactions associated with B cell lymphoma" is one of mode of action of the anti-CD80 antibodies. The claimed inventions of "treating patients with B cell lymphoma with the claimed CD80-specific antibodies" of both applications anticipate one another.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant will consider filing a terminal disclaimer, when the instant application is in condition for allowance.

9. Claims 29-41 and 43-55 are directed to an invention not patentably distinct from claims 23-26, 32 and 37 of commonly assigned USSN 09/758,173 for the reasons above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP ∋ 2302). Commonly assigned, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office Action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Phillip Gambel, PhD.
Primary Examiner
Technology Center 1600
November 15, 2005